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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/584,651	04/17/2007	Borut Furlan	33578US-PCT	5011

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EXAMINER	
KATAKAM, SUDHAKAR	

ART UNIT	PAPER NUMBER
1621	

MAIL DATE	DELIVERY MODE
10/07/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/584,651	FURLAN ET AL.	
	Examiner	Art Unit	
	SUDHAKAR KATAKAM	1621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 July 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-4* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-4* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/28/09 has been entered.

Status of the application

2. Receipt of Applicant's remarks and arguments filed on 7/28/09 is acknowledged.

3. In view of applicants' amendments, and upon further consideration, a new ground(s) of rejection is made in view of different interpretation of the previously applied reference, and provide an explanation of the rejection.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

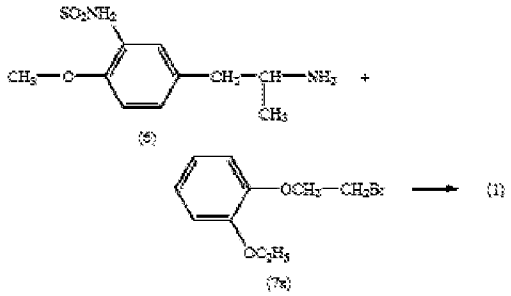
> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

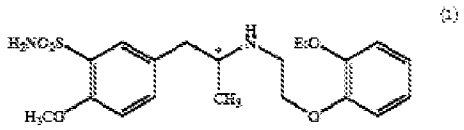
1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 2-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Hoorn et al** (US 6,835,853).

Hoorn et al teach preparation of enriched tamsulosin free base by condensation of the racemic amine (6) with a bromo-compound (7a) in refluxing methanol [see below, or col. 14],



, where (1) is represented by the following structure:



[col. 1]. Optionally tamsulosin free base may be converted to tamsolosin hydrochloride [col.14, lines 56-61]. **Hoorn et al** also teach that the tamsulosin hydrochloride at more than a 99.9% purity in their process [see Example 7].

The differences between the **Hoorn et al** and instant claims are as follows:

(i) **Hoorn et al** fails to teach molar excess of 1-(2-bromoethoxy)-2-ethoxybenzene in the process;

(ii) **Hoorn et al** fails to teach measurable amount of overalkylated products and their amount less than 0.1% in their process.

With regard to (i) of above, **Hoorn et al** suggested, in Example 2A, 200 g of amine compound and 100.3 g of bromo-compound in the preparation of tamsulosin. However, the concentrations of reactants are optimizable for a given reaction process. Moreover, the purity of the tamsulosin hydrochloride at more than a 99.9% in the process of **Hoorn et al**, which also reads the purity of the claimed process. Applicants are invited to provide a showing which is commensurate in scope with the claimed invention that clearly demonstrate that the claimed concentration range result in some unexpected property over the prior art.

With regard to (ii) of above, **Hoorn et al** teach 99.9% purity of tamsulosin hydrochloride in their preparation process. Since the prior art teaches same starting materials and end product, the remaining 0.1% consists of overalkylated products. It is expected that the impurities would be similar. Because the patent office is not equipped with the ability to make the determination of the amount of overalkylated products remaining in the tamsulosin hydrochloride in the prior art, the burden is shifted to the applicant to establish an unexpected result and make a comparison with the cited prior art.

Therefore, it would be prima facie obvious to one of ordinary skill in the art at the time of the invention, to isolate tamsulosin hydrochloride containing less than 0.1% of overalkylated products. One of ordinary skill in the art would be motivated isolate pure tamsulosin hydrochloride, with the reasonable expectation that the compound would show increased potency in the treatment of cardiac insufficiencies and improved pharmacological activities. Absent any showing of unusual and/or unexpected results over Applicant's particular tamsulosin hydrochloride, the art obtains the same effect on the purity of tamsulosin hydrochloride in the prior art. One of ordinary skill in the art would be motivated to optimize these parameters to arrive at the instantly claimed invention since it is within the purview of a skilled person in the art. The expected results would be an efficient production of tamsulosin hydrochloride for the pharmaceutical industry.

7. The prior art made of record and not relied upon is considered pertinent to applicants' disclosure. **Fujikura et al** (AT 397 960, see applicants IDS dated 6/26/06) teach tamsulosin hydrochloride with an approximate 99.95 purity (calculated from the difference in elemental analysis between "calculated" and "found" on page 9, lines 19-25).

Response to Arguments

8. Applicant's arguments filed on 7/28/09 have been fully considered but they are not persuasive.

The examiner acknowledges applicants' argument that **Hoorn et al** or **Fujikara et al** fails to teach molar excess of 1-(2-bromoethoxy)-2-ethoxybenzene in the preparation of tamsulosin hydrochloride.

The examiner contends, however, that the concentrations of reactants are optimizable for a given reaction process. Moreover, the purity of the tamsulosin hydrochloride at more than a 99.9% in the process of **Hoorn et al** or **Fujikara et al**, which also reads the purity of the claimed process. Applicants are invited to provide a showing which is commensurate in scope with the claimed invention that clearly demonstrate that the claimed concentration range result in some unexpected property over the prior art. Merely modifying the process conditions such as temperature and concentration is not a patentable modification absent a showing of criticality. In re Aller, 220 F.2d 454, 105 U.S.P.Q. 233 (C.C.P.A. 1955).

Conclusion

9. No Claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sudhakar Katakam whose telephone number is 571-272-9929. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Daniel Sullivan can be reached on 571-272-079. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Sudhakar Katakam/
Examiner, Art Unit 1621